Complete Summary

GUIDELINE TITLE

PET imaging in melanoma: recommendations.

BIBLIOGRAPHIC SOURCE(S)

Petrella T, Walker-Dilks C. PET imaging in melanoma: recommendations. Toronto (ON): Cancer Care Ontario (CCO); 2009 Jan 19. 24 p. (Recommendation report - PET; no. 3). [19 references]

GUIDELINE STATUS

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the <u>Cancer Care Ontario Web site</u> for details on any new evidence that has emerged and implications to the guidelines.

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Melanoma

GUIDELINE CATEGORY

Diagnosis Evaluation Management Technology Assessment

CLINICAL SPECIALTY

Dermatology Nuclear Medicine Oncology Radiation Oncology Radiology Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate:

- What benefit to clinical management does positron emission tomography (PET) or positron emission tomography/computed tomography (PET/CT) contribute to the diagnosis or staging of melanoma?
- What benefit to clinical management does PET or PET/CT contribute to the assessment of treatment response for melanoma?
- What benefit to clinical management does PET or PET/CT contribute when recurrence of melanoma is suspected but not proven?
- What benefit to clinical management does PET or PET/CT contribute to restaging at the time of documented recurrence for melanoma?
- What is the role of PET when a solitary metastasis is identified at the time of recurrence and the metastasectomy is being contemplated?

TARGET POPULATION

Patients with melanoma

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Positron emission tomography (PET)
- 2. Positron emission tomography/computed tomography (PET/CT)

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of positron emission tomography (PET) and positron emission tomography/computed tomography (PET/CT)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Systematic Review

A systematic review of the published literature was undertaken (see details below). This was conducted by one clinical lead author, nominated by the Provincial Melanoma Disease Site Group (DSG) and a Program in Evidence-Based Care (PEBC) methodologist. The systematic review served as the evidentiary foundation for a set of draft recommendations developed by this team.

Literature Search

A scoping review undertaken by the PEBC methodologist to identify any existing systematic reviews on positron emission tomography (PET) imaging in the cancers of interest yielded such a review. The U.K. Health Technology Assessment (HTA) systematic review (referred to as the HTA review from this point forward) evaluated the effectiveness of fludeoxy-glucose (FDG) PET imaging in several selected cancers, including melanoma. The document included systematic reviews and individual primary studies dating from 2000 to August 2005. Because the HTA review sufficiently covered the questions and methodologies of interest to this recommendation report, its results were used for the evidence base from 2000 to August 2005, and its search strategies were performed in MEDLINE and EMBASE to update the literature to June 2008. The update strategies for MEDLINE and EMBASE are in Appendices 1 and 2 in the original guideline document, respectively.

Study Selection Criteria

All systematic reviews and primary studies in the HTA review that addressed the questions of interest in this recommendation report (diagnosis, staging, treatment response, recurrence, and restaging) were included. The inclusion criteria of the HTA review were employed to select systematic reviews and primary studies identified in the update search.

The inclusion criteria for systematic reviews included in the HTA review and used in the update were:

- Dedicated to FDG PET in the selected cancers in humans
- Contained evidence related to diagnostic accuracy, change in patient management, clinical outcomes, or treatment response

The inclusion criteria for primary studies included in the HTA review and used in the update were:

- Prospective clinical study of dedicated FDG PET in a single cancer of interest
- Study published after the search date of a robust systematic review covering that cancer management decision
- Study published as a full article in a peer-reviewed journal

- Study reported evidence related to diagnostic accuracy, change in patient management, or clinical outcomes
- Study included ≥ 12 patients with the cancer of interest
- Study used a suitable reference standard (pathological confirmation and clinical follow-up) when appropriate

The citations and abstracts from the update searches were reviewed by the PEBC research coordinator and marked as relevant or not relevant, according to the inclusion criteria from the HTA review, and were classified by disease site. The research coordinator and the clinical lead for each Disease Site Group reviewed the relevant citations and full text of the articles for the final decision on inclusion.

NUMBER OF SOURCE DOCUMENTS

The Health Technology Assessment (HTA) review results for melanoma included two systematic reviews and 17 primary studies. The 2005 to 2008 update included nine primary studies.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Health Technology Assessment (HTA) review did not pool individual studies. Data were extracted into separate tables for systematic reviews and primary studies for each type of management decision. The same approach was used for data extraction for the evidence from August 2005 to June 2008. Full text and data extractions of the studies from the update search were provided to the clinical lead authors to aid in the formulation of the recommendations. Telephone conferences and email correspondence between the clinical leads and the Program in Evidence-based Care (PEBC) methodologist took place to clarify details and answer questions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Consensus by the Provincial Melanoma Disease Site Group (DSG)

The draft recommendations were refined during a DSG teleconference. The Melanoma DSG is comprised of medical oncologists, surgeons, and pathologists and supported by a Program in Evidence-Based Care (PEBC) research methodologist.

DSG Consensus Process

The clinical lead author wrote summaries of the key evidence, draft recommendations, and qualifying statements for the questions pertaining to diagnosis/staging, assessment of treatment response, and recurrence/restaging. The ensuing documents were circulated to all members of the Melanoma DSG and were discussed during a teleconference. The recommendations generated during this process are referred to below as the DRAFT DSG Recommendations. The intent of these recommendations was to guide discussion at the consensus meeting.

Provincial Positron Emission Tomography (PET) Imaging Consensus Meeting

The draft recommendations were vetted at a larger provincial PET imaging consensus meeting co-hosted by Cancer Care Ontario and the Provincial PET Steering Committee. The meeting was facilitated and supported by members of the PEBC team. Participants included representatives of the PEBC DSGs, other clinical experts in the areas of nuclear and diagnostic medicine, members of the Cancer Care Ontario clinical leadership team, and representatives from the Ontario PET Steering Committee and the Ontario Health Technology Assessment Committee.

Provincial Consensus Process

The consensus meeting on 19 September 2008 was conducted as follows:

- Consensus meeting participants sat at tables specifically set up to discuss a
 particular disease site (colorectal, esophageal, head & neck, and melanoma).
 The melanoma table held the clinical lead and any other Melanoma DSG
 members attending, in addition to other invited health professionals.
- The recommendations and summary of key evidence drafted by the clinical lead and refined and confirmed by the Melanoma DSG were presented by the clinical lead to the group at the colorectal table.
- During the small-group discussion at the Melanoma table in the morning and discussion among the entire consensus meeting participants in the afternoon, the recommendations underwent further refinement and modification. The attendees voted on the revised recommendations to indicate their extent of agreement on a scale from 1 to 9 (1 indicating strong agreement, 5 indicating no agreement or disagreement, and 9 indicating strong disagreement).

After the consensus meeting, the exact wording of the recommendations was slightly modified for consistency with the recommendations resulting from the other disease discussions. These modifications included using emphatic, unambiguous language (i.e., *PET is recommended...*) and removing the need to distinguish between PET and positron emission tomography/computed tomography [PET/CT]. It was made clear at the consensus meetings that PET

imaging alone is being phased out and PET/CT imaging is the current standard. Thus, the term PET is used to cover PET and PET/CT imaging.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis/Staging

- Positron emission tomography (PET) is recommended for staging of high-risk patients with potentially resectable disease.
- PET is not recommended for the diagnosis of sentinel lymph node micrometastatic disease or for staging of I, IIa, or IIb melanoma.
- The routine use of PET or positron emission tomography/computed tomography (PET/CT) is not recommended for the diagnosis of brain metastases.
- The routine use of PET is not recommended for the detection of primary uveal malignant melanoma.

Assessment of Treatment Response

A recommendation cannot be made for or against the use of PET for the assessment of treatment response in malignant melanoma due to insufficient evidence.

Recurrence/Restaging

A recommendation cannot be made for or against the use of PET for routine surveillance due to insufficient evidence.

Solitary Metastasis Identified at Time of Recurrence

PET is recommended for isolated metastases at time of recurrence or when contemplating metastasectomy.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

These recommendations are based on an evidentiary foundation consisting of one recent high-quality U.K. Health Technology Assessment systematic review that included systematic review and primary study literature for the period from 2000 to August 2005 and an update of that systematic review undertaken to retrieve the same level of evidence for the period from August 2005 to June 2008.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of positron emission tomography/computed tomography (PET/CT) imaging in melanoma

Refer to the original guideline document for key evidence supporting the recommendations for use.

POTENTIAL HARMS

False positive and false negative results

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Diagnosis/Staging

Criteria for high risk include lymph node metastases, deep head and neck melanoma, and evidence of satellitosis or in-transit metastases. These include patients with American Joint Committee on Cancer (AJCC) Stage IIC and III disease.

Disclaimer

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IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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Petrella T, Walker-Dilks C. PET imaging in melanoma: recommendations. Toronto (ON): Cancer Care Ontario (CCO); 2009 Jan 19. 24 p. (Recommendation report - PET; no. 3). [19 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2009 Jan 19

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-Based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Melanoma Disease Site Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

For a current list of past and present members, please see the <u>Cancer Care</u> Ontario Web site.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Cancer Care Ontario Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI Institute on April 26, 2010.

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